K120890

Shen Wei USA Inc.
33278 Central Ave. Suite 102
Union City, CA.94587

## 510(k) Summary

AUG 17 2012

**1.0 Submitter:**

Name: Shen Wei USA Inc.
Address: 33278 Central Ave. Suite 102
Union City, CA. 94587

Phone No: 510-429-8692
Fax No: 510-487-5347

**Manufacturer:**

Name: ZHANGJIAGANG JIAMEI RUBBER PRODUCTS CO., LTD
Address: FENGHUANG TOWN,
ZHANGJIAGANG CITY, CHINA 215614

Phone No: 520-845-0023
Fax No: 520-845-0311

Date 510k Summary was prepared: July 8th, 2012

**2.0 Contact Person:**

Name: Albert Li
Phone No: 510-429-8692
Fax No: 510-487-5347

**3.0 Name of the device:**

Trade Name: Powder-Free Nitrile Examination Gloves, Orange Color
Device Name: Powder-Free Nitrile Examination Gloves, Orange Color
Common Name: Patient Examination Gloves
Classification Name: Patient examination glove (21 CFR 880.6250, Product Code FMC)
Product Code: Nitrile -80LZA

**4.0 Predicate Device Information:**

The predicate device is K090194, Powder-Free Nitrile Examination Gloves, Black Color, 07/07/2009. Class I Powder Free Nitrile Examination gloves, 80LZA, that meets all requirements of ASTM D 6319-10 and FDA 21 CFR 800.20.

**5.0 Description of the Device Modification:**

The Powder-Free Nitrile Examination Gloves, Orange is substantial equivalent to Powder-Free Nitrile Examination Gloves, Black Color with 510k number K090194 that is currently marketed. The device modification is a change in color from Black to Orange. Another device modification is the addition of adding a citric acid coating to the interior surface of the gloves to achieve a pH of 5.0 – 5.5 for the inner surface of the glove.

**6.0 Labeling and Intended Use of the Device:**

Draft labels for Powder-Free Nitrile Examination Gloves, Orange can be found in Attachment 1. The only change to labeling is before it was labeled black glove and now the present labels being labeled orange glove and added "@ pH 5.0-5.5".

The Powder-Free Nitrile Examination Gloves, Orange Color is a disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. This device is single use only. Indication for Use Statement can be found in Attachment 2.

**7.0 Summary of the Technological Characteristics of the Device**

The Powder-Free Nitrile Examination Gloves, Orange Color are summarized with the following technological characteristics compared to ASTM or equivalent standards.

| Characteristics | Standards | Device Performance |
|---|---|---|
| Dimensions | ASTM D6319-10 | Meets |
| Physical Properties | ASTM D6319-10 | Meets |
| Freedom from pinholes | ASTM D6319-10<br>FDA 21 CFR 800.20 | Meets, AQL 2.5 |
| Powder-Free | ASTM D 6124-06 | Meets < 2mg/glove |
| Biocompatibility | Primary Skin Irritation in Rabbits | Passes<br>(Not a primary skin irritant) |
| | Dermal Sensitization | Passes (Not a contact sensitizer) |

The test methods used are the same as those submitted in the original submission. A declaration of conformity with design controls is included in Attachment 3.

**8.0 Conclusion:**

The Powder-Free Nitrile Examination Gloves, Orange Color will perform according the glove performance standards referenced in section 7.0 above and meet ASTM standards, and FDA requirements for water leak test on pinhole

AQL. Also, this device is substantial equivalent in safety and performance to currently marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Shen Wei (USA), Incorporated
Mr. Albert Li
Director of Compliance
33278 Central Avenue, Suite 102
Union City, California 94587

AUG 17 2012

Re: K120890
Trade/Device Name: Powder-Free Nitrile Examination Gloves, Orange Color
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: July 13, 2012
Received: July 17, 2012

Dear Mr. Li:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**Attachment Two**

# INDICATION FOR USE

**Applicant:** Shen Wei (USA) Inc.

**Device Name:** Powder-Free Nitrile Examination Gloves, Orange Color

**Indication For Use:**

A disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. This device is **single use only**.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

**Prescription Use** _____ OR **Over-The Counter** ___X___
Per 21CFR 801.109 (Optional Format 1-2-96)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K120890